MR 308325



North American HSE SERVICES

December 3, 2007

US Environmental Protection Agency
OPPT Document Control Office (Mail Code 7407)
1200 Pennsylvania Ave, NW
EPA East Room 6428
Washington, DC 20460
ATTN: Section 8(e) Coordinator

RE: FYI Notification: AG-RHO FKC 10001

Dear Sir or Madam:

07 DEC -6 /// 10: 24

Contain NO CBI



In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), Rhodia Inc. (Rhodia) is making the Agency aware of certain information on the above-referenced product. Rhodia does not believe the information is reportable under the terms of Section 8(e) of TSCA. However, for the reasons stated below, we believe it is appropriate that we provide this for your information.

Rhodia is having conducted a dose range-finding study for a Combined Repeated Dose Toxicity Study with a Reproduction/Developmental Toxicity Screening test (OECD 422) using rats treated with doses of 0, 33, 100, 300 and 1000 mg/kg/day. Recently, the testing laboratory reported in an email message that all 3 male rats and 1 female rat in the highest dose group (1000 mg/kg/day) were found dead the morning after the first dose was administered. Shortly afterwards, the other 2 females in this dose group also died. All rats that died were found to have gas in their stomachs and small intestines.

No mortality or moribundity was observed in any rats in any other dosage groups.

Since these lethality effects occurred at the limit dose which exceeded a Maximum Tolerated Dose, Rhodia does not believe that these results meet the EPA's reporting criteria for TSCA Section 8(e). However, these data could meet the reporting criteria of FIFRA Section 6(a)(2), as this study (and the definitive study that will follow this range-finding study) will be used to support the use of this product as an inert ingredient in pesticide formulations, and the information contained in this letter may be considered to be new. Because submissions under FIFRA Section 6(a)2 require EPA registered numbers of active ingredients or end-use formulations and this product does not have such a number, we could not submit under FIFRA Section 6(a)2.

These preliminary results were first reviewed by Rhodia on November 5, 2007. Rhodia asserts that none of the information contained within this notice constitutes confidential business information. Should you have any questions, or require any further information, please call (215) 369-9734. Thank you.

Very truly yours,

RHODIA INC.

Judjth L. Kranetz

Manager, Regulatory Compliance

JLK/

Atts

Ref: 07-0047L.doc

Fed Ex A/B #8614-5479-5118

¹ This material is identified as a mixture of: Dodecanaminium, N-(carboxymethyl)-N,N-dimethyl-, hydroxide, inner salt (CAS# 683-10-3, 20%), Tetradecanaminium, N-(carboxymethyl)-N,N-dimethyl-, hydroxide, inner salt (CAS# 2601-33-4, 7%), Potassium chloride (CAS# 7447-40-7, 8%), and water (CAS# 7732-18-5)

CN 7500 Cranbury, New Jersey 08512

Document Processing Desk – 6(a)(2) – Fed Ex A/B #8614-5479-5107 Office of Pesticide Programs Room 266A Crystal Mall #2 1921 Jefferson Davis Highway Arlington, VA 22202